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(54) **METHODS AND DEVICES FOR VASCULAR ACCESS**

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CPC **A61M 25/104** (2013.01); **A61B 17/22**
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See application file for complete search history.

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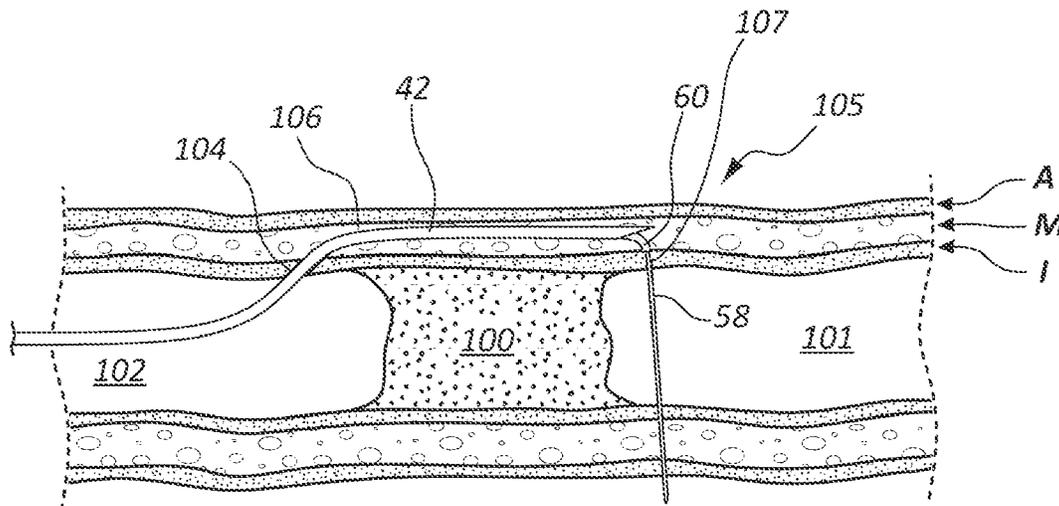
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(57) **ABSTRACT**

Methods and devices for treating occlusive peripheral vas-
cular diseases are described. The devices can include an
access catheter having a guidewire lumen and stylet lumen,
a guide tube having a curved distal end, a stylet, and an
actuator handle. The methods describe techniques for using
the described devices for performing vascular procedures,
such as subintimal angioplasty.

22 Claims, 13 Drawing Sheets



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| (52) | U.S. Cl. CPC <i>A61M 2025/0095</i> (2013.01); <i>A61M 2025/0096</i> (2013.01); <i>A61M 2025/0197</i> (2013.01); <i>A61M 2039/0258</i> (2013.01) | |
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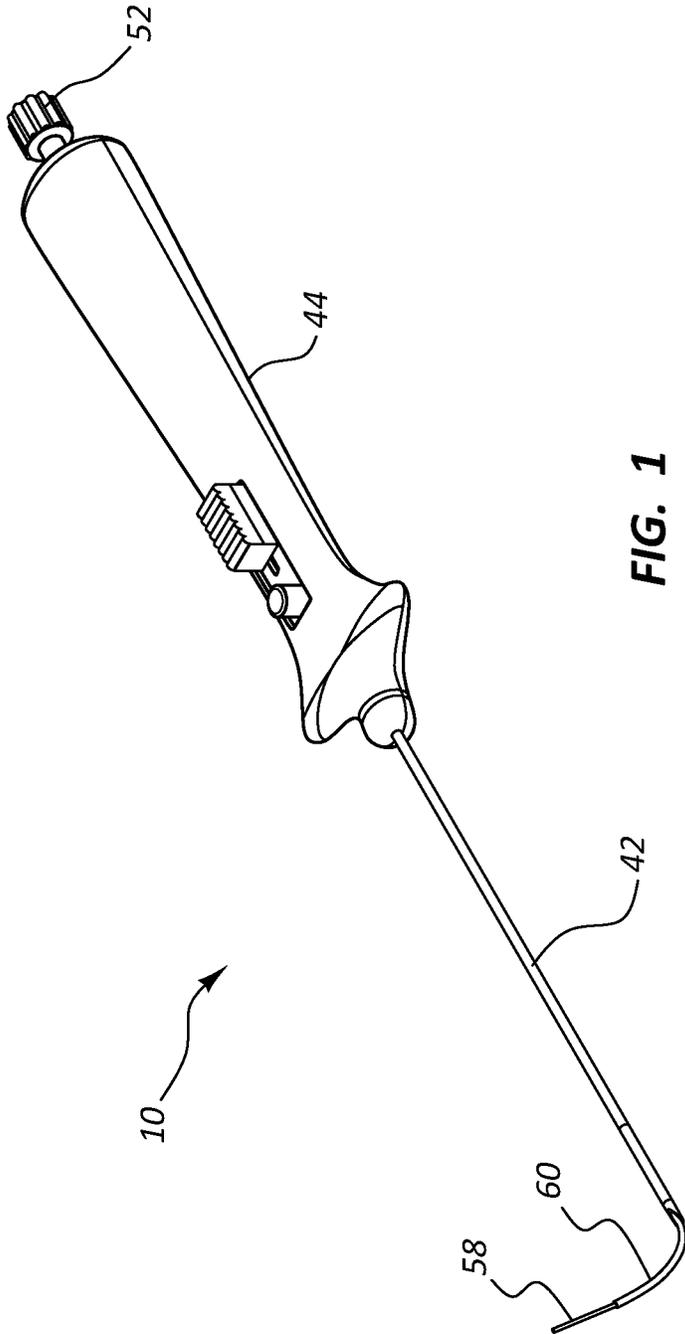


FIG. 1

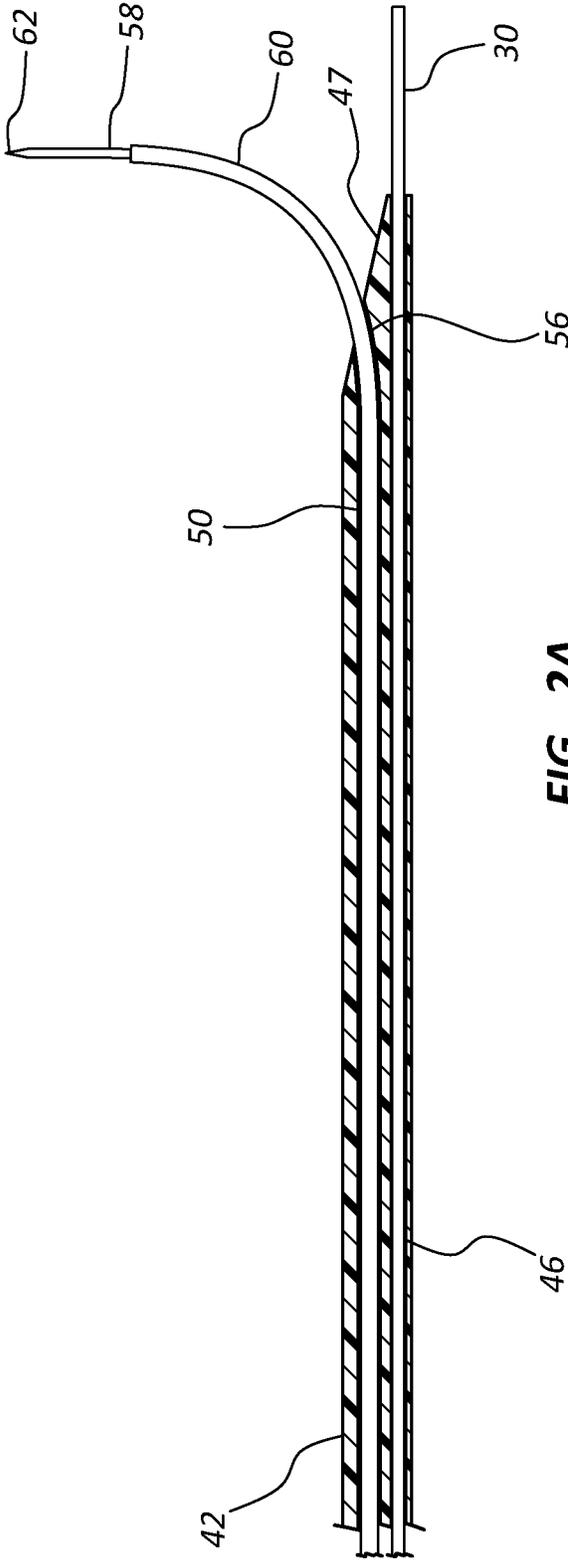


FIG. 2A

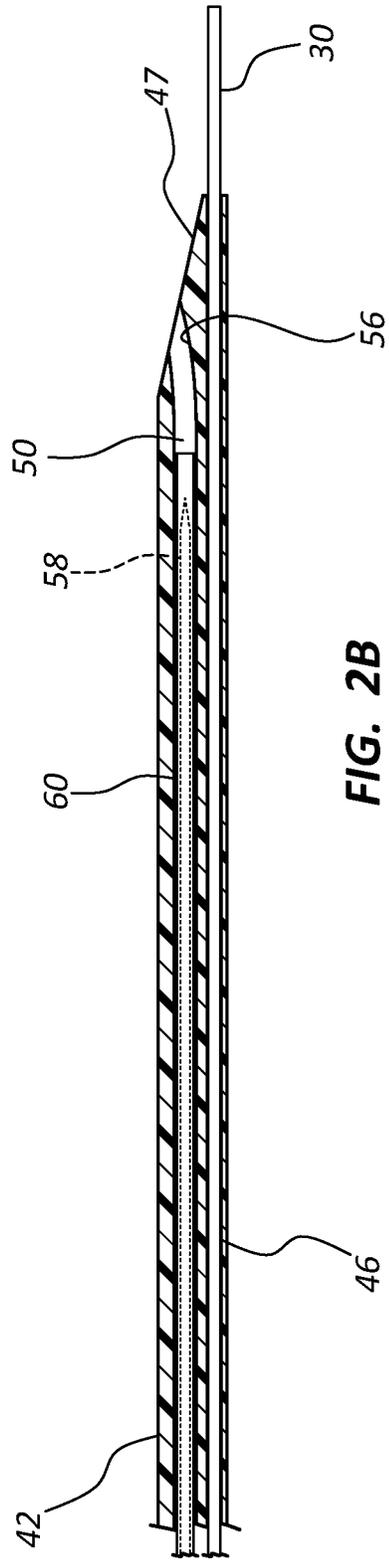


FIG. 2B

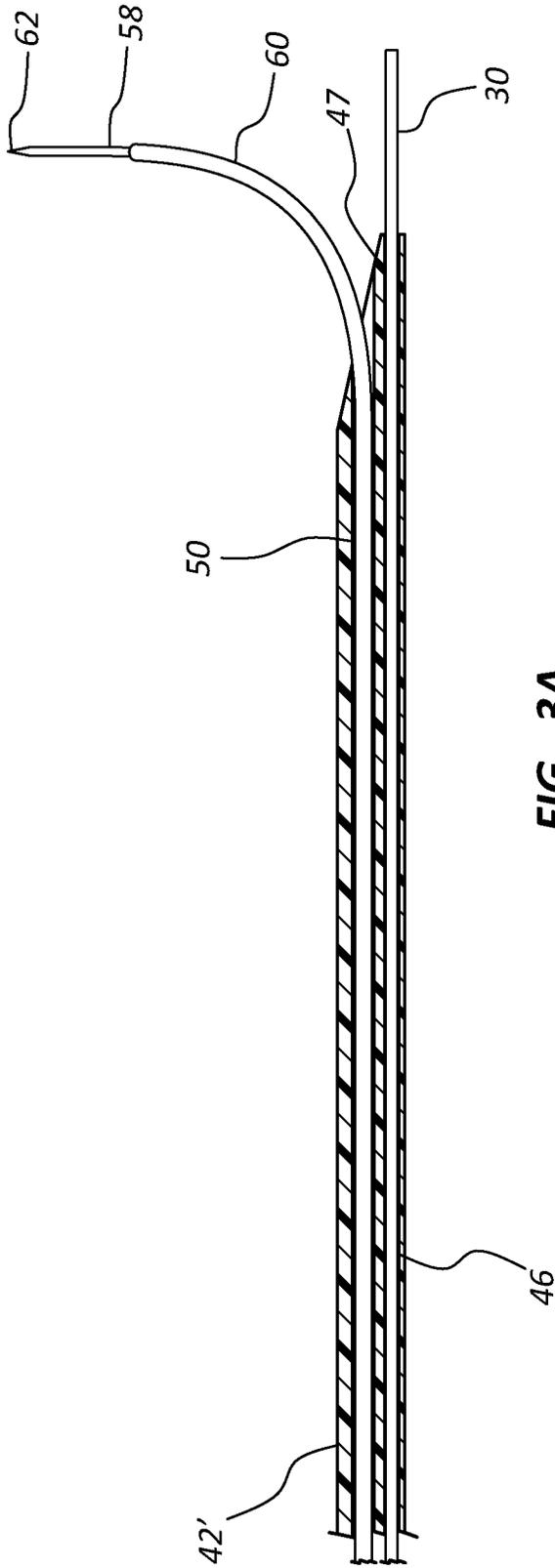


FIG. 3A

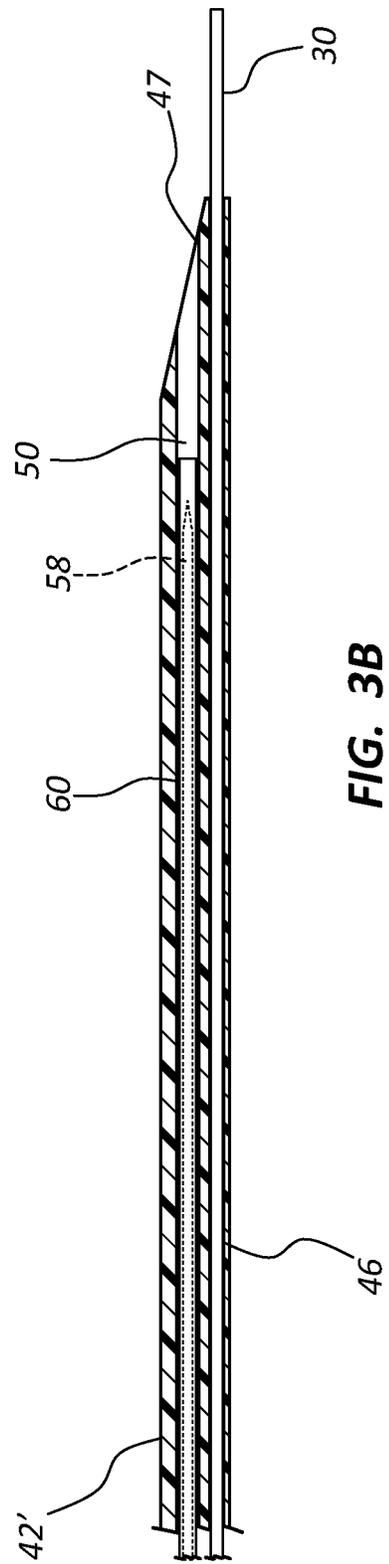


FIG. 3B

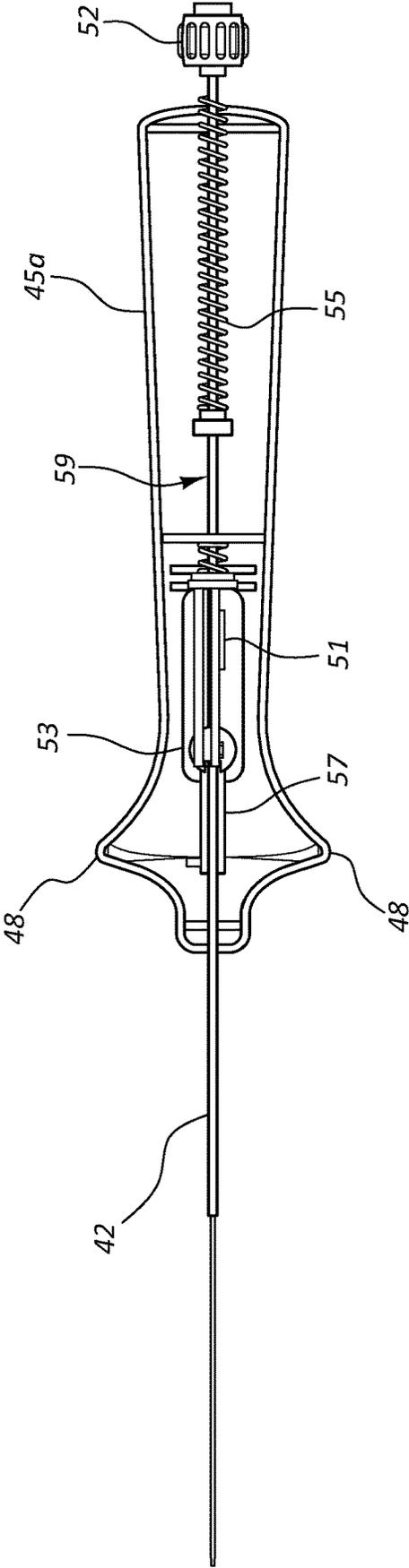


FIG. 4A

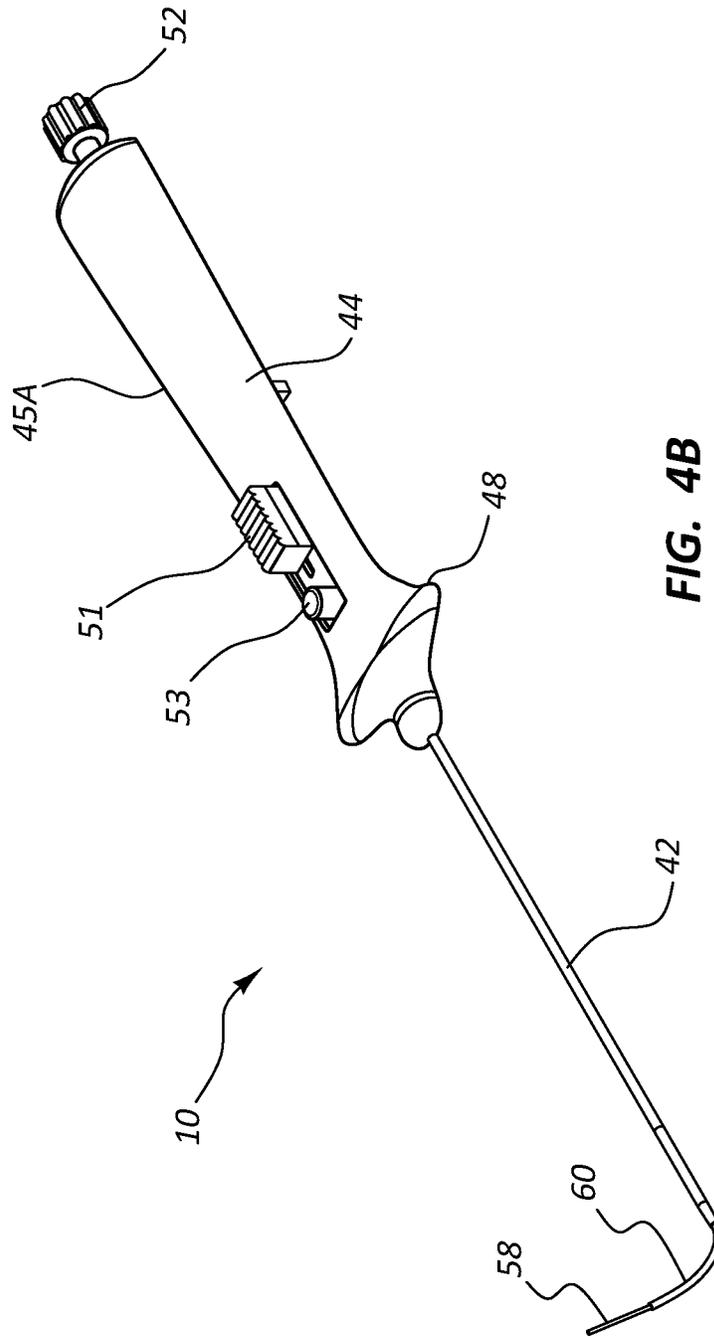
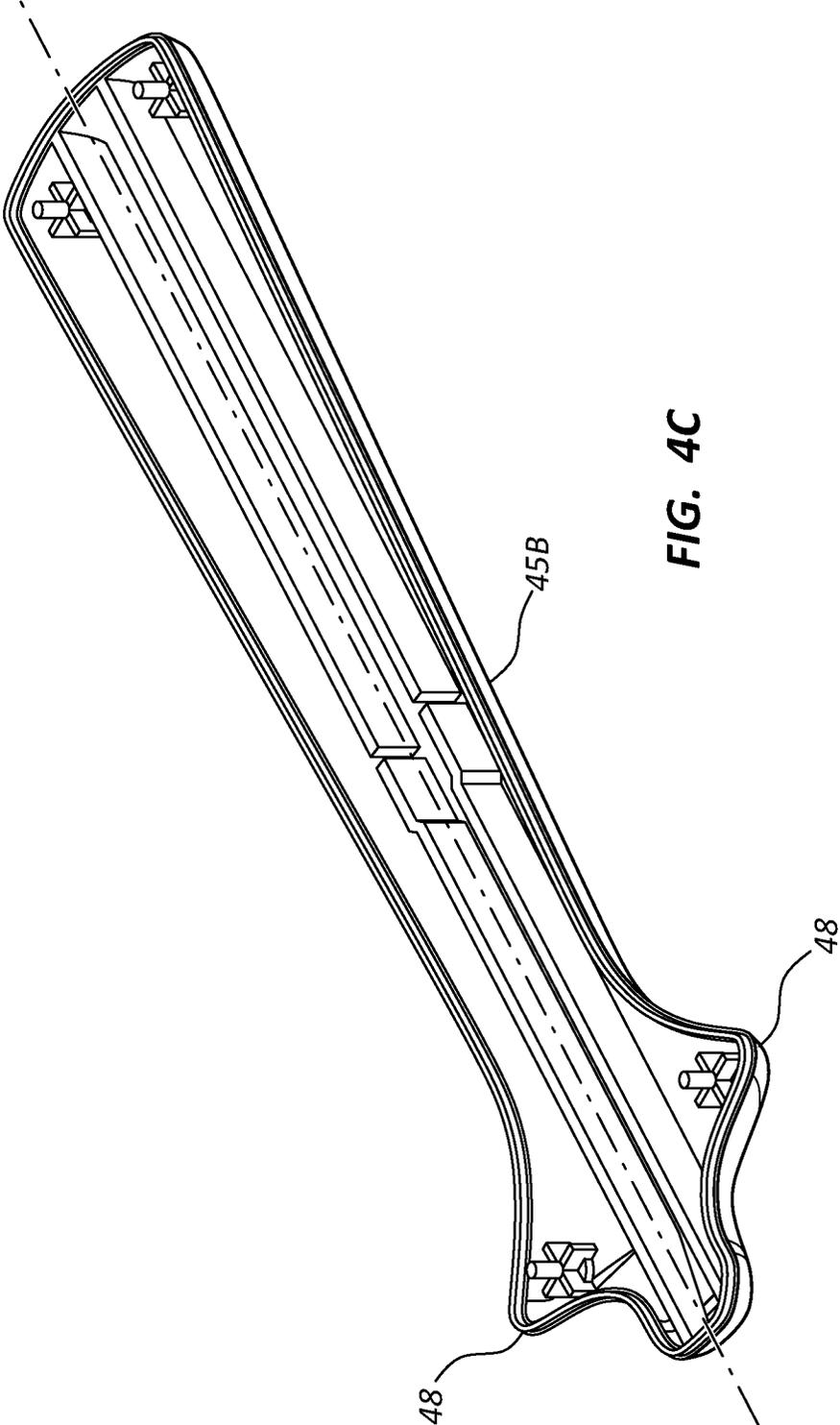


FIG. 4B



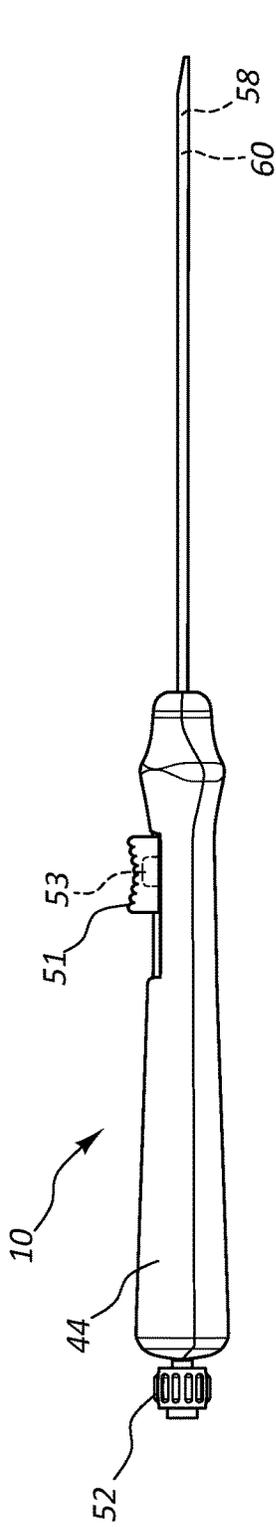


FIG. 5A 45B

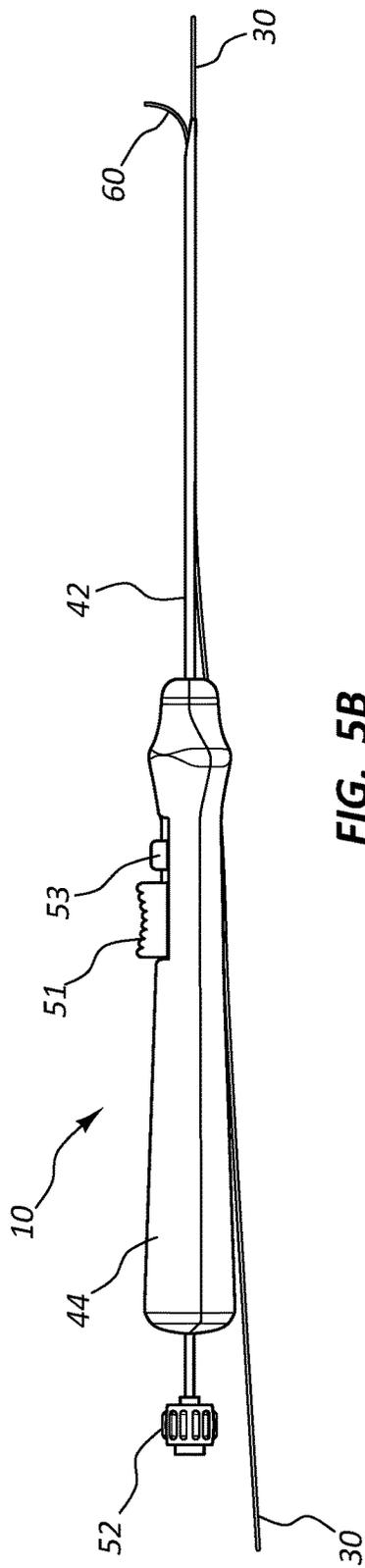


FIG. 5B

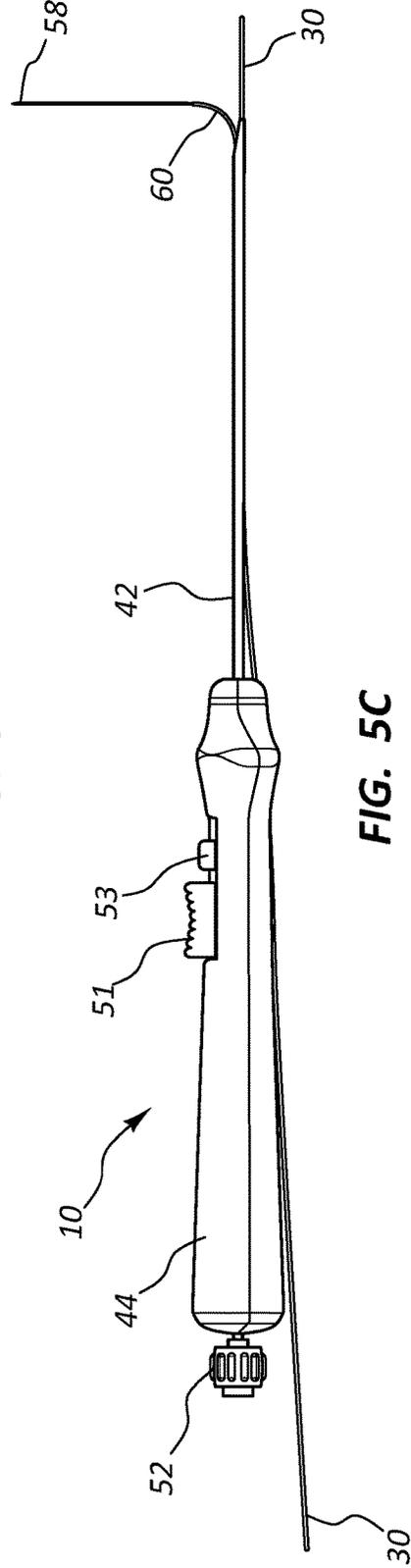


FIG. 5C

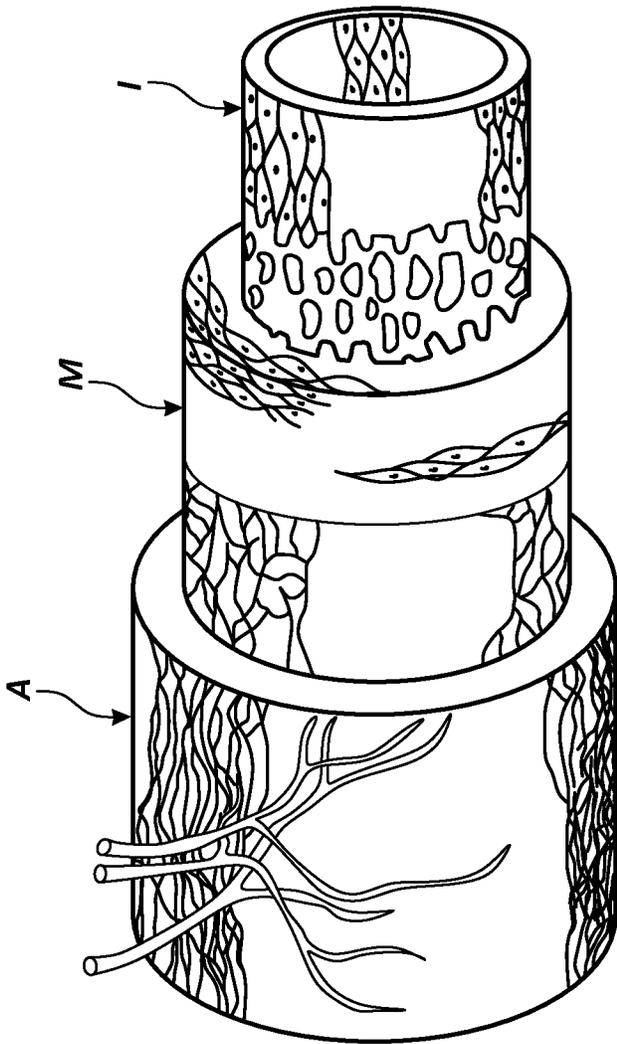


FIG. 6

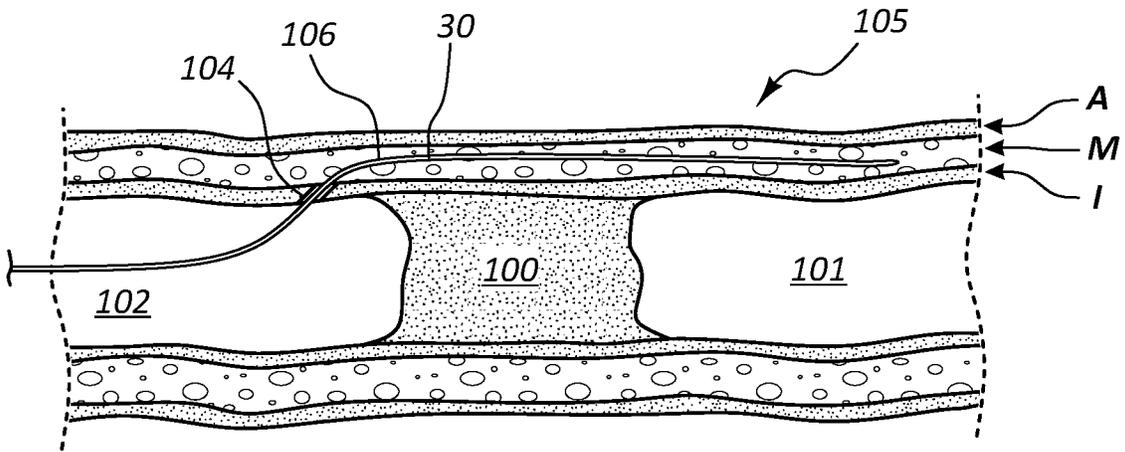


FIG. 7A

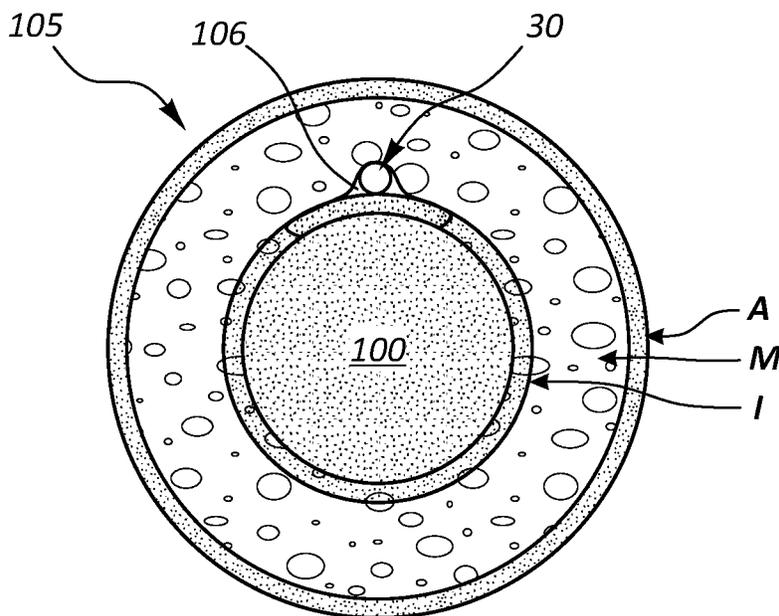


FIG. 7B

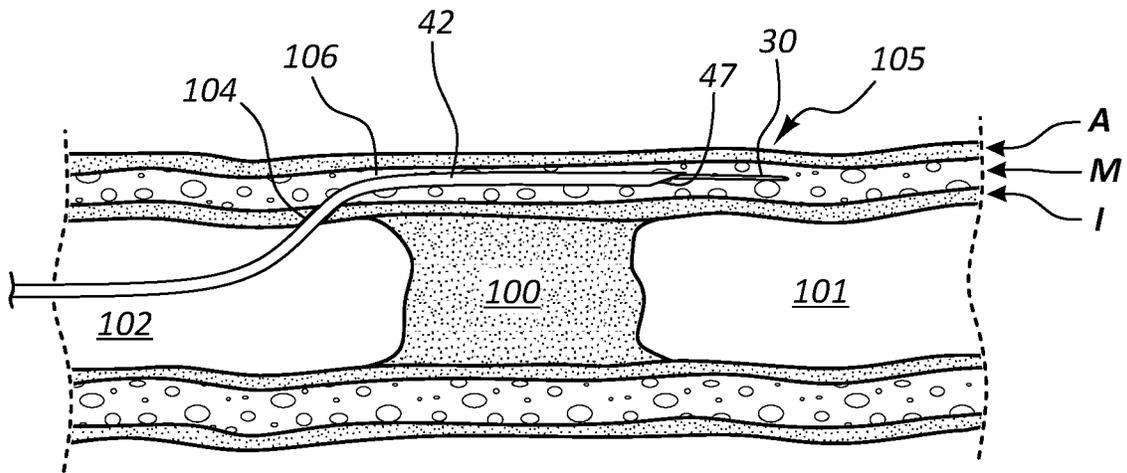


FIG. 7C

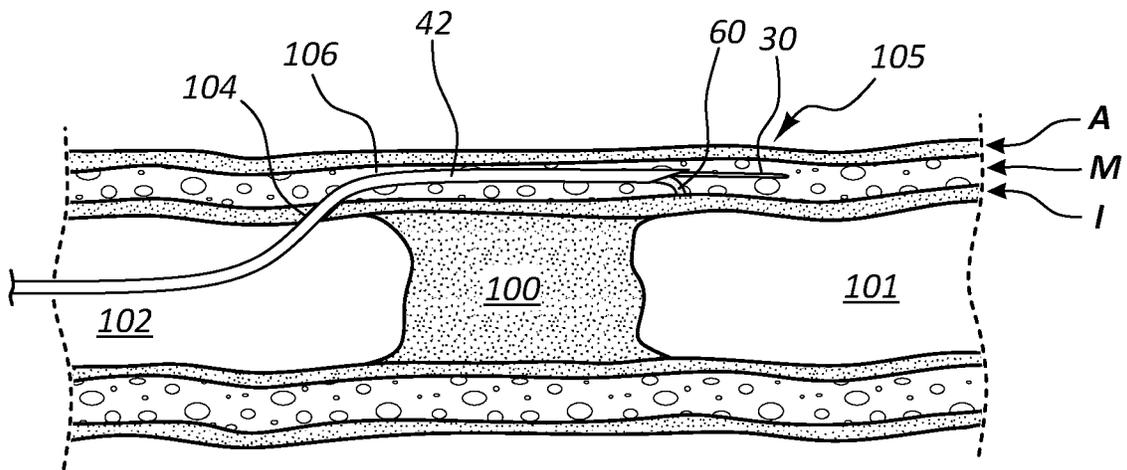


FIG. 7D

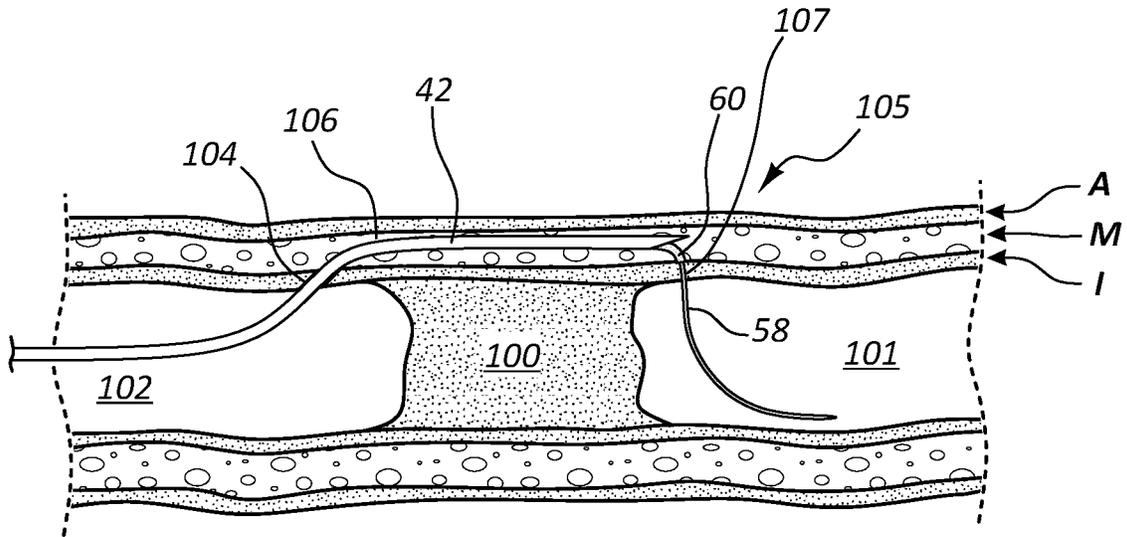


FIG. 7E

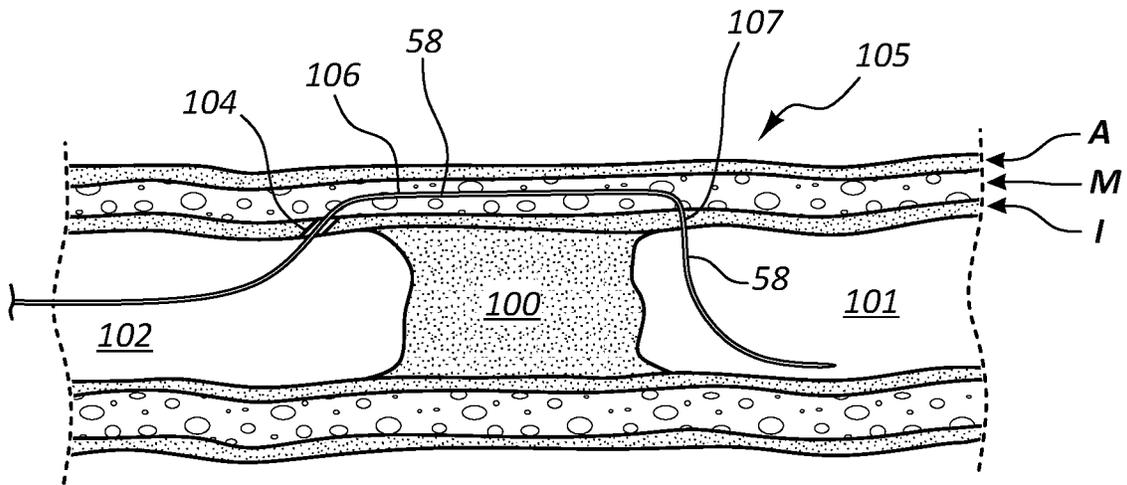


FIG. 7F

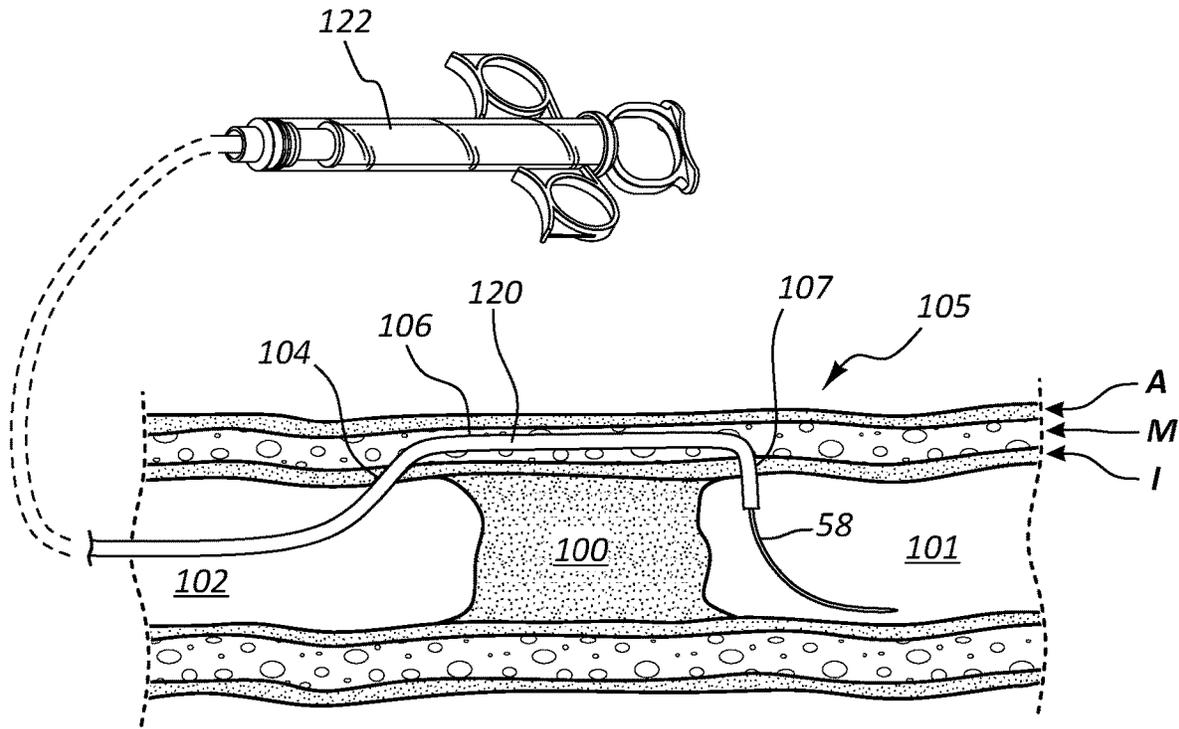


FIG. 7G

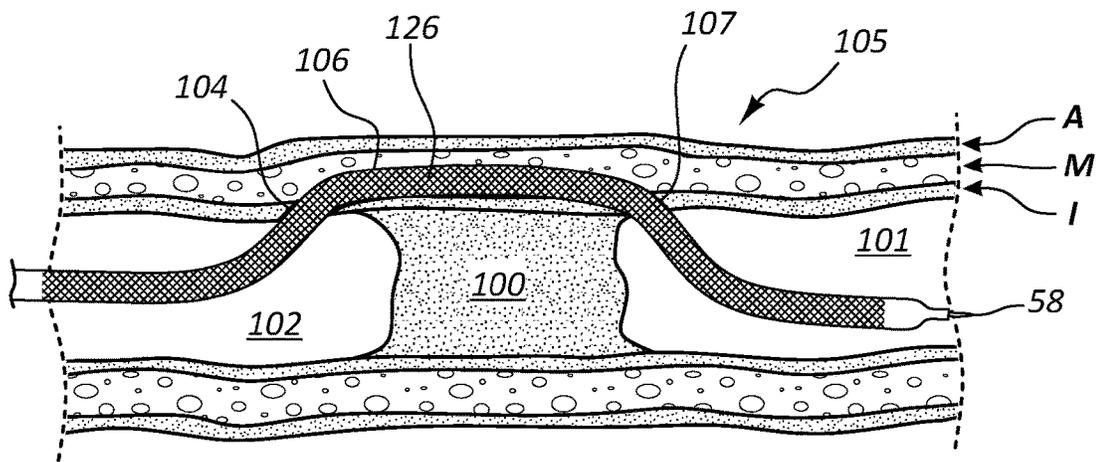


FIG. 7H

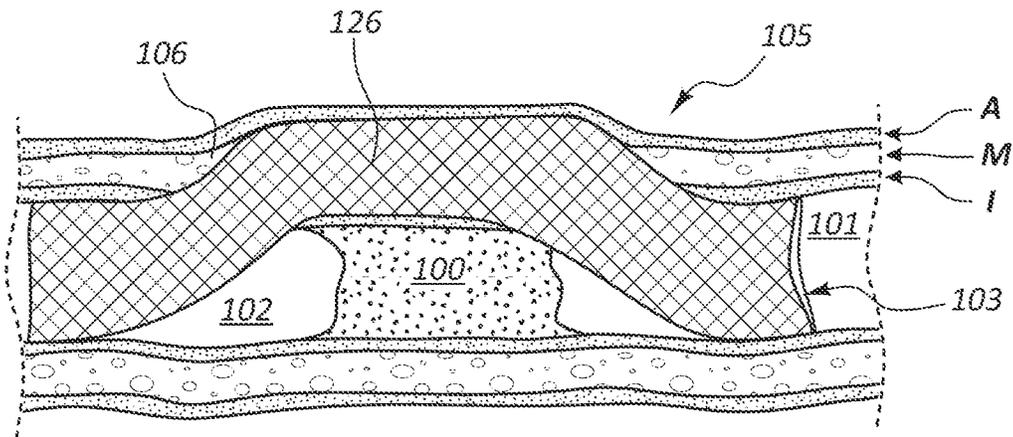


FIG. 7I

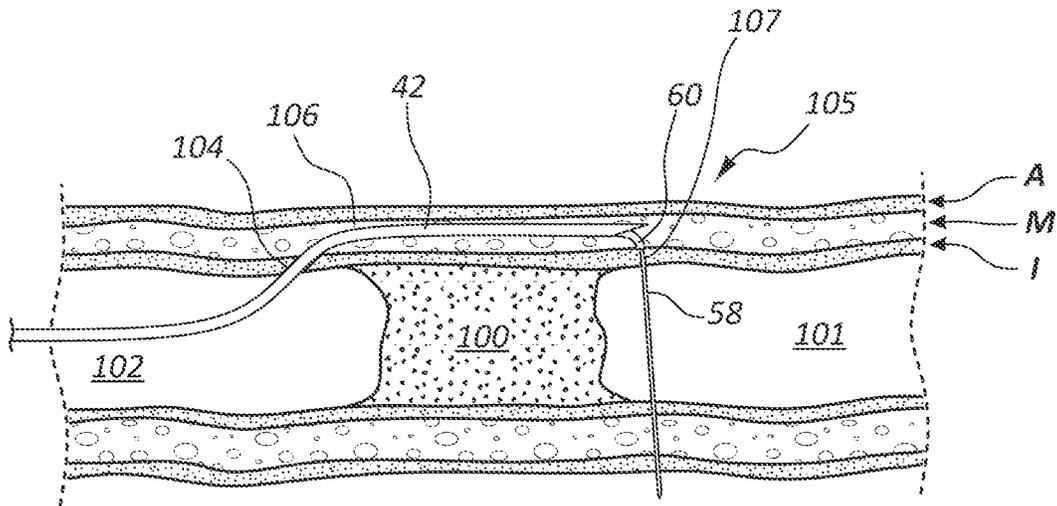


FIG. 7J

METHODS AND DEVICES FOR VASCULAR ACCESS

RELATED CASES

This application claims priority to U.S. Provisional Application No. 62/432,359, filed on Dec. 9, 2016 and titled "METHOD AND DEVICE FOR PERFORMING SUBINTIMAL ANGIOPLASTY," which is hereby incorporated by reference in its entirety.

TECHNICAL FIELD

The present disclosure relates to devices and methods for vascular access, including the treatment of patients with vascular disease. More specifically, in some embodiments, the present disclosure relates to devices and methods to treat patients with occluded peripheral arteries, including treatments comprising subintimal angioplasty techniques.

BRIEF DESCRIPTION OF THE DRAWINGS

The written disclosure herein describes illustrative embodiments that are non-limiting and non-exhaustive. Reference is made to certain of such illustrative embodiments that are depicted in the figures, in which:

FIG. 1 is a perspective view of an access device.

FIG. 2A is a side view of a cross-section of a portion of the access device of FIG. 1 in a first configuration with an extended guide tube and stylet, the access device comprising a ramped surface.

FIG. 2B is a side view of a cross-section of a portion of the access device of FIG. 1 in a second configuration with a retracted guide tube and stylet, the access device comprising a ramped surface and.

FIG. 3A is a side view of a cross-section of a portion of another embodiment of an access device in a first configuration with an extended guide tube and stylet.

FIG. 3B is a side view of a cross-section of a portion of the access device of FIG. 3A in a second configuration with a retracted guide tube and stylet.

FIG. 4A is a bottom view of the access device of FIG. 1 with a portion of the handle removed to show internal components.

FIG. 4B is a perspective view of a top portion of the handle and other components of the access device of FIG. 1 configured with the guide tube and stylet advanced.

FIG. 4C is a perspective view of a bottom portion of the handle of the access device of FIG. 1.

FIG. 5A is a side view of the access device of FIG. 1 prior to advancement of the guide tube.

FIG. 5B is a side view of the access device of FIG. 1 following deployment of the guide tube and loading of a spring loading mechanism.

FIG. 5C is a side view of the access device of FIG. 1 following deployment of the stylet.

FIG. 6 is a perspective view of a sectioned artery wall.

FIG. 7A is a cross-sectional view, taken through a plane including the longitudinal axis of the artery, of a portion of an artery showing a guidewire being advanced into a subintimal space of the artery along an occlusion.

FIG. 7B is a cross-sectional view of a portion of the artery of FIG. 7A, taken through a plane perpendicular to the cross-sectional plan of FIG. 7A, showing the guidewire advanced into the intimal space along the occlusion.

FIG. 7C is a cross-sectional view of the artery of FIG. 7A, taken through the cross-sectional plane of FIG. 7A, showing

an access catheter of the access device of FIG. 1 within the subintimal space along the occlusion.

FIG. 7D is a cross-sectional view of the artery of FIG. 7A, taken through the cross-sectional plane of FIG. 7A, showing the guide tube of the access device deployed from a distal end of the access catheter.

FIG. 7E is a cross-sectional view of the artery of FIG. 7A, taken through the cross-sectional plane of FIG. 7A, showing the stylet of the access device deployed from the guide tube into an arterial lumen beyond the occlusion.

FIG. 7F is a cross-sectional view of the artery of FIG. 7A, taken through the cross-sectional plane of FIG. 7A, showing the stylet of the access device in the arterial lumen after removal of the access catheter.

FIG. 7G is a cross-sectional view of the artery of FIG. 7A, taken through the cross-sectional plane of FIG. 7A, showing a distal end of a second catheter in the arterial lumen.

FIG. 7H is a cross-sectional view of the artery of FIG. 7A, taken through the cross-sectional plane of FIG. 7A, showing a distal end of a balloon in the arterial lumen and a stent within the subintimal space.

FIG. 7I is a cross-sectional view of the artery of FIG. 7A, taken through the cross-sectional plane of FIG. 7A, showing the expanded stent forming a blood flow lumen along the occlusion.

FIG. 7J is a cross-sectional view of the artery of FIG. 7A, taken through the cross-sectional plane of FIG. 7A, showing a distal end of the stylet disposed within tissue surrounding the artery.

DETAILED DESCRIPTION

The present disclosure describes access devices and methods for providing a second entry point to a vessel, the second entry point remote from a first entry point. The devices and methods of the present disclosure may be used to treat occlusive peripheral vascular disease by facilitating subintimal angioplasty. In some embodiments, access devices within the scope of this disclosure include systems comprising: a vascular catheter having first and second lumens, the first lumen being adapted to receive a vascular guidewire; a guide tube disposed in the second lumen, the guide tube having a distal end with a preformed curve; a stylet disposed in the guide tube, the stylet having a sharp distal tip configured to pierce vascular tissue; a guide tube actuator operatively connected to the guide tube or vascular catheter, the guide tube actuator configured to produce relative movement between the guide tube and the vascular catheter; and a stylet actuator operatively connected to the stylet, the stylet actuator having a stylet advancement mechanism. Access devices within the scope of this disclosure may provide a system for accessing an artery beyond an occlusion and forming a blood flow lumen through subintimal space along the occlusion.

Embodiments may be understood by reference to the drawings, wherein like parts are designated by like numerals throughout. It will be readily understood by one of ordinary skill in the art having the benefit of this disclosure that the components of the embodiments, as generally described and illustrated in the figures herein, could be arranged and designed in a wide variety of different configurations. Thus, the following more detailed description of various embodiments, as represented in the figures, is not intended to limit the scope of the disclosure, but is merely representative of various embodiments. While the various aspects of the embodiments are presented in drawings, the drawings are not necessarily drawn to scale unless specifically indicated.

In the following disclosure, various features are sometimes grouped together in a single embodiment, figure, or description thereof for the purpose of streamlining the disclosure. Many of these features may be used alone and/or in combination with one another. The phrases “coupled to” and “in communication with” refer to any form of interaction between two or more entities, including mechanical, electrical, magnetic, electromagnetic, fluid, and thermal interaction. Two components may be coupled to or in communication with each other even though they are not in direct contact with each other. For example, two components may be coupled to or in communication with each other through an intermediate component.

The directional terms “distal” and “proximal” are given their ordinary meaning in the art. That is, the distal end of a medical device means the end of the device furthest from the practitioner during normal use. The proximal end refers to the opposite end, or the end nearest the practitioner during use. As specifically applied to the access device of the present disclosure, the proximal end of the access device refers to the end nearest the handle and the distal end refers to the opposite end, the end nearest the tip of the catheter. Further, if at one or more points in a procedure a physician changes the orientation of an access device, as used herein, the term “proximal end” always refers to the handle end of the access device (even if the distal end is temporarily closer to the physician).

References to approximations are made throughout this specification, such as by use of the term “substantially.” For each such reference, it is to be understood that, in some embodiments, the value, feature, or characteristic may be specified without approximation. For example, where qualifiers such as “about” and “substantially” are used, these terms include within their scope the qualified words in the absence of their qualifiers. For example, where the term “substantially perpendicular” is recited with respect to a feature, it is understood that in further embodiments, the feature can have a precisely perpendicular configuration.

FIGS. 1-5C show various embodiments of devices for treating an occlusion in a blood vessel. For example, the devices disclosed in FIGS. 1-6B may be used in performing subintimal angioplasty. The devices shown in FIGS. 1-5C and described in the present disclosure are similar to those shown in U.S. Pat. No. 9,220,874, the disclosure of which is incorporated herein by reference. As indicated above, FIGS. 1-5C are not necessarily drawn to scale.

Referring to FIG. 1, an access device 10 may comprise a vascular access catheter or first catheter 42, a handle or actuator 44, a guide tube or cover tube 60, and a stylet 58. The access catheter 42 may be coupled to and extend from the handle 44. The length and diameter of the access catheter 42 may depend on a treatment or anatomy for which the access catheter 42 is intended for use. For example the length of the access catheter may be configured to traverse the distance between a desired entry point into an artery and the location of an occluded portion of the artery. In some embodiments, the length of the access catheter 42 may range from 20 cm to 150 cm, including from 50 cm to 100 cm. The diameter of the access catheter 42 may range from 5 Fr to 9 Fr, including from 6 Fr to 8 Fr.

Referring to FIGS. 2A-3B, which illustrate a portion of the access device 10 comprising a distal portion of the access catheter 42 in FIGS. 2A and 2B and an analogous portion of an alternative embodiment of an access catheter 42' in FIGS. 3A and 3B. The access catheters 42 and 42' are shown in cross-section, while the elements disposed within the access catheters are not in cross-section for clarity. The access

catheter 42' of FIGS. 3A and 3B is identical to access the catheter 42 of FIGS. 2A and 2B except that access catheter 42' does not comprise a ramped surface as further detailed below. Accordingly, other elements of the access device of FIG. 1 as shown in FIGS. 3A and 3B (such as guidewire 30) retain the same numerals as the embodiment of FIGS. 1, 2A and 2B. Disclosure recited in connection with access catheter 42 of FIGS. 2A and 2B may be analogously applied to access catheter 42' of FIGS. 3A and 3B.

With continued reference to FIGS. 2A-3B as well as the access device of FIG. 1, the access catheter 42 may comprise a guidewire lumen 46 and a stylet lumen 50. In some embodiments, the guidewire lumen 46 and the stylet lumen 50 may be configured as a single lumen. The guidewire lumen 46 may be sized to receive any suitably sized guidewire, such as 0.014 inch, 0.018 inch, 0.035 inch, etc. The guidewire lumen 46 may be configured as a rapid exchange (RX) guidewire lumen for receiving a guidewire 30. For example, the guidewire lumen 46 may comprise a port adjacent a proximal portion that is configured to receive the guidewire 30. In other embodiments, a wall of the guidewire lumen 46 may be slit adjacent the proximal portion such that the guidewire 30 can be slipped into the guidewire lumen 46 via the slit. Further, in certain embodiments, the guidewire lumen 46 may extend to a proximal end of the access catheter 42 and the guidewire 30 may be advanced through a port (not shown) of the handle 44 into the guidewire lumen 46. Additionally, the guidewire 30 can be introduced into the guidewire lumen 46 using an introducer kit (not shown).

The stylet lumen 50 may extend from the handle 44 to an opening 54 adjacent the distal end of the access catheter 42. In some embodiments, the stylet lumen 50 curves or is ramped at its distal end to form a camming surface 56 as shown in the embodiment of FIGS. 2A and 2B. The camming surface 56 can provide additional structural support and curving guidance to the guide tube 60 when the guide tube 60 is advanced into an extended position. In some embodiments the stylet lumen 50 does not have a curved camming surface. For example, the stylet lumen 50 can be substantially straight adjacent its distal end as illustrated in the embodiment of FIGS. 3A and 3B.

The access catheter 42 comprises a catheter tip 47 at the distal end of the access catheter 42. The catheter tip 47 may be tapered, beveled, conical, or comprise other shapes or structures. In some embodiments the catheter tip 47 includes a radiopaque marker configured to be visible under fluoroscopy. The radiopaque marker can be embedded in the catheter tip 47. In some embodiments the shape of the radiopaque marker can be selected to facilitate fluoroscopic identification of the location and orientation of the catheter tip 47. Examples of radiopaque marker materials include gold, platinum, platinum-iridium, and other biocompatible radiopaque materials.

The guide tube 60 may be concentrically disposed within the stylet lumen 50 of the access catheter 42. The guide tube 60 may be operatively coupled to the handle 44 and extend from the handle 44 toward the distal end of the access catheter 42. A distal end of the guide tube 60 may be positioned adjacent the catheter tip 47 prior to actuation of the handle 44 as illustrated in the configurations of FIGS. 2B and 3B. In some embodiments, the guide tube 60 may extend beyond the catheter tip 47 following actuation of the handle 44, such as in the configurations shown in FIGS. 2A and 3A. In other embodiments, the guide tube 60 may not extend beyond the catheter tip 47 following actuation of the handle 44, such as embodiments wherein the stylet 58 extends

beyond the catheter tip **47** (as further detailed below) but the guide tube **60** remains within the stylet lumen **50** after actuation.

As illustrated in FIGS. **2A** and **3A**, in some embodiments, the guide tube **60** comprises a preformed curve or bend of substantially 90 degrees at the distal end of the guide tube **60**. The range of the angle of the curve or bend may be from 15 degrees to 120 degrees, including 75 degrees to 105 degrees. In some embodiments, a camming surface **56** of the stylet lumen **50** (see the embodiment of FIGS. **2A** and **2B**) can promote the curvature of the guide tube **60**.

The guide tube **60** may be formed of any suitable material such as nickel titanium, shape memory metal, superelastic metal, stainless steel, thermal plastic, etc. The outside diameter of the guide tube **60** may be configured such that the guide tube **60** can be slidably disposed within the stylet lumen **50**. The inside diameter of the guide tube **60** may be configured such that a stylet **58** can be slidably disposed within the guide tube **60**. For example, the guide tube **60** may be a nitinol hypotube having an outer diameter of 0.025 inch and an inside diameter greater than 0.014 inch such that an 0.014 inch diameter stylet can be disposed with the guide tube **60**.

In some embodiments, the stylet **58** may be concentrically disposed within the guide tube **60**. The stylet **58** may be operatively coupled to the handle **44** and extend from the handle **44** toward the distal end of the access catheter **42**. A distal end of the stylet **58** may be positioned adjacent the distal end of the guide tube **60** prior to actuation of the handle **44** as illustrated in FIGS. **2B** and **3B**. In some embodiments, the stylet **58** may extend beyond the distal end of the guide tube **60** following actuation of the handle **44** as illustrated in FIGS. **2A** and **3A**.

The stylet **58** may comprise a sharp distal point **62** adapted to penetrate tissue and other material, such as blood vessel walls and occlusions. The sharp distal point **62** may comprise any suitable design, such as faceted, pencil point, etc. The stylet **58** may be formed of any suitable material such as nickel titanium, shape memory metal, superelastic metal, stainless steel, thermal plastic, etc. The outside diameter of the stylet **58** may be configured such that the stylet **58** can be slidably disposed within the guide tube **60**. For example, the stylet **58** may be a nitinol wire having an outer diameter of 0.014 inch.

Referring to FIGS. **4A-4C**, in some embodiments the handle **44** can comprise a top portion **45A**, a bottom portion **45B**, a slide button **51**, and a stylet actuator **59**. FIG. **4A** is a bottom view of the handle **44** with the bottom portion **45B** removed to show internal components and the inside of the top portion **45A**. FIG. **4B** illustrates top view of the handle **44** configured with the guide tube **60** and stylet **58** advanced. FIG. **4C** illustrates the bottom portion **45B** of the handle **44**.

The top portion **45A** and bottom portion **45B** can engage to form the handle **44**. The handle **44** may comprise wings **48** on opposing sides of the handle **44**. The wings **48** can be used to apply a distal force to the access catheter **42** from the handle **44** and/or to otherwise manipulate the device.

In some embodiments, a proximal end of the access catheter **42** may be operatively coupled to the slide button **51** via a catheter slide **57**. In use, the slide button **51** and catheter slide **57** may be displaced proximally causing the access catheter **42** to be displaced proximally such that the distal end of the guide tube **60** extends from the distal end of the access catheter **42** and assumes a curved shape. (As noted above, the guide tube **60** may be shape-set or otherwise biased to form a curved shape and assume that curved shape when unconstrained by the access catheter **42**.) In

other embodiments, a proximal end of the guide tube **60** may be operatively coupled to the slide button **51**. In such embodiments, the slide button **51** may be displaced distally causing the guide tube **60** to be displaced distally such that the distal end of the guide tube **60** extends from the distal end of the access catheter **42** and assumes its curved shape as illustrated in FIG. **4B**.

Referring to FIGS. **5A-5C** as well as the components shown in FIG. **4**, in certain embodiments, a proximal portion of the stylet **58** may be operatively coupled to the stylet actuator **59**. The stylet actuator **59** may comprise a spring release button **53**, a spring loading mechanism **52**, and a spring **55** as illustrated in FIG. **4A**. The stylet actuator **59** may be configured to displace the stylet **58** such that the distal end of the stylet **58** is displaced through vessel wall tissue and into a vessel lumen. In use, the stylet actuator **59** can be loaded by displacing the spring loading mechanism **52** proximally such that the spring **55** is compressed and the spring loading mechanism **52** is releasably locked in a proximal position. The slide button **51** may cover the spring release button **53** when the access device **10** is in a pre-ready configuration as illustrated in FIG. **5A**. The slide button **51** may be displaced proximally, as described previously, such that the spring release button **53** is exposed, such as the configuration shown in FIG. **5B**. The spring release button **53** may be positioned either proximal to or distal to the slide button **51**. Displacement of the spring release button **53** causes the spring **55** to decompress. The spring loading mechanism **52** is displaced distally as the spring **55** is decompressed. The stylet **58**, which is coupled to the spring loading mechanism **52**, is displaced distally such that the distal end of the stylet **58** extends from the distal end of the guide tube **60** as illustrated in FIG. **5C**.

The access device **10** may be used to perform a variety of vascular procedures, such as transjugular vein carotid artery access, retrograde jugular vein access, bypass graft placement, subintimal angioplasty, etc.

One exemplary procedure shown in FIGS. **6-7I** is a subintimal angioplasty procedure to treat an occluded artery **105**. FIGS. **7A-7I** show the artery in cross-section with the elements of the access device disposed in various locations during the procedure. The access device is not shown in cross-section for clarity. The cross-sectional plane for FIGS. **7A** and **7C-7I** is a plane that includes the longitudinal axis of the artery, while the cross-sectional plane of FIG. **7B** is a cross-sectional plane that cuts laterally across the artery, perpendicular to the plane of FIGS. **7A** and **7C-7I**.

Subintimal angioplasty procedures may be performed in various portions of the vasculature, including vasculature within a leg of a patient. As illustrated in FIG. **6** the wall of the artery to be treated is comprised of three layers. The inner layer is the tunica intima I. The middle layer is the tunica media T, which is the thickest layer. The outer layer is the tunica adventia A. These layers are labeled using the same designations in FIGS. **7A-7I**.

As shown in FIGS. **7A-7B** during the procedure, a guidewire **30** is inserted into a lumen **102** of the occluded artery **105** under fluoroscopic guidance. The guidewire **30** is directed to penetrate the tunica intima I and is advanced into a subintimal space **106** through a subintimal access site **104**. The guidewire **30** is advanced further to reach beyond an occlusion **100**, to the position shown in FIG. **7A**. As illustrated in FIG. **7B** the guidewire **30** creates and is disposed within a subintimal space **106** between the tunica intima I and tunica media M layers.

Referring to FIG. **7C**, the access catheter **42** of the access device **10** may then be advanced over the guidewire **30** and

positioned such that the catheter tip **47** is beyond the occlusion **100**. In some embodiments, the guidewire **30** is removed through the guidewire lumen **46** of the access catheter **42**. In other embodiments, the guidewire **30** remains in place.

Prior to advancing the guide tube **60**, the access catheter **42** may be oriented such that the guide tube **60** will be directed toward the tunica intima I of the occluded artery **105**. To help ensure that the guide tube **60** will be directed toward the tunica intima I and a portion of a lumen **101** beyond the occlusion **100**, the orientation of the extended guide tube **60** can be determined based on the orientation of the handle **44**. For example, in the illustrated embodiment of FIGS. **1** and **4A**, the slide button **51** is substantially perpendicular to a plane defined by the opposing wings **48** that extends along a length of the handle **44** (the plane defined by the curve where the top portion **45A** of the handle **44** contacts the bottom portion **45B** of the handle **44**). The guide tube **60** may be directed to curve in the same orientation as the slide button **51** when the guide tube **60** extends from the distal end of the access catheter **42** (see FIG. **4A**). For example, if the slide button **51** is oriented upwards, the guide tube **60** will be oriented upwards as it extends from the access catheter **42**. In certain embodiments, the orientation of the guide tube **60** may be visually verified. For example, fluoroscopy may be used to verify orientation of the guide tube **60**. Further, as noted above, a radiopaque marker or other indicia may be used to verify the orientation of the access catheter **42**.

With the access catheter disposed as shown in FIG. **7A**, the slide button **51** is displaced proximally as shown in FIG. **5B**, such that the guide tube **60** is displaced distally and extends from the access catheter **42**. This results in the configuration shown in FIG. **7D**. In some embodiments, the slide button **51** may be displaced proximally such that the access catheter **42** is displaced proximally and the guide tube **60** extends from the access catheter **42** in the pre-formed curve shape. As illustrated in FIG. **7D**, the guide tube **60** may thus be directed toward the tunica intima I by the pre-formed curve at the distal end of the guide tube **60**. In some embodiments, the guide tube **60** may be directed toward the tunica intima I by the camming surface **56** of the access catheter **42**. In some embodiments, the distal end of the guide tube **60** is positioned adjacent the tunica intima I. In other embodiments, the distal end of the guide tube **60** may be disposed within the lumen **101**.

The stylet actuator **59** may be loaded by proximally displacing the spring loading mechanism **52**. The stylet actuator **59** may be activated by depressing the spring release button **53** of the handle **44**. After actuation, the stylet **58** may then be disposed in the configuration shown in FIG. **7E**. As shown in FIG. **7E**, the distal end of the stylet **58** may penetrate the tunica intima I creating a subintimal exit site **107** and is displaced into the lumen **101**.

The subintimal exit site **107** may be understood as second arterial access site with the first arterial access site being the site the artery **105** is accessed for insertion of the first catheter **42** into the artery **105**. In some procedures, for example as shown in FIG. **7J**, the distal end of the stylet **58** may penetrate the wall of the occluded artery **105** opposite the access catheter **42** such that the distal end of the stylet **58** may be disposed within tissue surrounding the occluded artery **105**.

Referring to FIG. **7F**, the stylet **58** may be decoupled from the handle **44** and the access catheter **42**, and guide tube **60** may be withdrawn from the occluded artery **105** over the stylet **58**. The stylet **58** is shown to enter the subintimal

space **106** through the subintimal access site **104**, extend through the subintimal space **106**, and exit the subintimal space **106** through the exit site **107**.

A second catheter **120** may be advanced over the stylet **58** such that the distal end of the second catheter **120** is disposed within the lumen **101** as shown in FIG. **7G**. The second catheter **120** may be coupled to a syringe **122** such that blood may be aspirated through a lumen of the second catheter **120**. The aspiration of blood through the second catheter **120** may be utilized to confirm that the distal end of the stylet **58** and the second catheter **120** are disposed within the lumen **101**. In certain embodiments, an X-ray contrast dye may be injected through the second catheter **120** into the lumen **101** and visualized using fluoroscopy to show blood movement and thereby confirm proper placement of the stylet **58** and end of the second catheter **120**. In some embodiments, the distal end of the stylet **58** may be disposed within tissue outside of the occluded artery **105**. In such embodiments, the second catheter **120** may be partially withdrawn until blood is aspirated through the second catheter **120**. The second catheter **120** may be withdrawn over the stylet **58** from the occluded artery **105**.

Referring to FIG. **7H**, a balloon catheter **125** comprising a stent **126** may be advanced into the occluded artery **105** over the stylet **58** such that a distal end of the balloon catheter **125** is disposed in the lumen **101**. The proximal end of the stent **126** may be positioned within the lumen **102**, a middle portion of the stent **126** may be within the subintimal space **106** and adjacent the occlusion **100**, and a distal end of the stent **126** may be positioned within lumen **101**.

Referring now to FIG. **7I**, the stent **126** may be expanded such that a blood flow lumen **103** is formed through the expanded stent **126** from the lumen **101** to lumen **102** within the subintimal space **106**. The occlusion **100** may be bypassed by the lumen **103** such that blood flows freely from the lumen **102** to the lumen **101**. In some embodiments, the occlusion **100** may be at least partially compressed as the stent **126** is expanded.

Access to the lumen **101** as shown in FIGS. **7F** and **7G** can be used to perform various procedures, including inflation of an angioplasty balloon to compress the occlusion, deployment of stents in other locations, and/or access and therapies at locations beyond the occlusion.

Without further elaboration, it is believed that one skilled in the art can use the preceding description to utilize the invention to its fullest extent. The claims and embodiments disclosed herein are to be construed as merely illustrative and exemplary, and not a limitation of the scope of the present disclosure in any way. It will be apparent to those having ordinary skill in the art, with the aid of the present disclosure, that changes may be made to the details of the above-described embodiments without departing from the underlying principles of the disclosure herein. In other words, various modifications and improvements of the embodiments specifically disclosed in the description above are within the scope of the appended claims. Moreover, the order of the steps or actions of the methods disclosed herein may be changed by those skilled in the art without departing from the scope of the present disclosure. In other words, unless a specific order of steps or actions is required for proper operation of the embodiment, the order or use of specific steps or actions may be modified. The scope of the invention is therefore defined by the following claims and their equivalents.

What is claimed is:

1. A method of treating an occlusion in an artery, the method comprising:

advancing a guidewire into a lumen of the artery and into a subintimal space of a wall of the artery adjacent the occlusion;

advancing a first catheter over the guidewire into the subintimal space;

advancing a stylet guide from the first catheter toward a portion of the lumen of the artery beyond the occlusion such that a distal end of the stylet guide is substantially orthogonal to an inner layer of the wall of the artery;

operating a first actuator to move a stylet along a curved path through the stylet guide, wherein the distal end of the stylet guide remains in the subintimal space when the stylet is displaced into the portion of the lumen of the artery beyond the occlusion, and

wherein a distal portion of the stylet guide comprises a preformed curve sized to be disposed within the subintimal space; and

penetrating the inner layer of the wall of the artery from the subintimal space with a distal end of the stylet into the lumen of the artery beyond the occlusion,

wherein the distal end of the stylet penetrates the wall of the artery opposite the first catheter such that the distal end of the stylet is disposed within tissue surrounding the artery.

2. The method of claim 1, wherein the first actuator is loaded by proximal displacement of a spring loading mechanism.

3. The method of claim 1, wherein operating the first actuator comprises releasing a spring coupled to the stylet.

4. The method of claim 1, wherein the stylet comprises a sharp distal end.

5. The method of claim 1, wherein the first catheter comprises a distal end comprising a ramped surface.

6. The method of claim 1, wherein the first catheter is coupled to a second actuator.

7. The method of claim 6, wherein the second actuator comprises a mechanism coupled to the stylet guide, wherein displacement of the mechanism displaces the stylet guide.

8. The method of claim 1, wherein the stylet is displaced distally relative to the stylet guide when operating the actuator.

9. The method of claim 1, further comprising:
orienting the first catheter such that the stylet guide is directed toward the portion of the artery beyond the occlusion when extended from the first catheter.

10. The method of claim 1, further comprising:
advancing a second catheter over the stylet, wherein a portion of the second catheter is within the subintimal space and a distal end of the second catheter is disposed within the portion of the lumen of the artery beyond the occlusion; and
aspirating blood through the second catheter to confirm that the distal end of the second catheter and the distal end of the stylet are disposed within the portion of the lumen of the artery beyond the occlusion.

11. The method of claim 1, further comprising:
advancing a balloon catheter comprising a stent over the stylet, wherein a portion of the stent is within the subintimal space adjacent the occlusion and a distal end of the balloon catheter is disposed within the portion of the lumen of the artery beyond the occlusion; and
expanding a balloon and the stent of the balloon catheter, wherein a bypass blood flow lumen is formed in the subintimal space adjacent the occlusion.

12. A method of performing subintimal angioplasty, the method comprising:
obtaining an access device comprising:

a handle;

a first actuator disposed within the handle comprising a spring mechanism; a first catheter coupled to the actuator;

a stylet guide comprising a curved distal end portion, wherein the stylet guide is concentrically disposed within the first catheter and longitudinally displaceable relative to the first catheter; and

a stylet concentrically disposed within the stylet guide and longitudinally displaceable relative to the stylet guide;

advancing a guidewire into a lumen of an artery and into a subintimal space of a wall of the artery adjacent an occlusion;

advancing the first catheter over the guidewire into the subintimal space;

advancing the stylet guide from the first catheter toward a portion of the lumen of the artery beyond the occlusion such that a distal end of the stylet guide is substantially orthogonal to an inner layer of the wall of the artery;

operating the first actuator to displace the stylet along a curved path through the stylet guide,

wherein the distal end of the stylet guide remains in the subintimal space when the stylet is displaced into the portion of the lumen of the artery beyond the occlusion, and

wherein a distal portion of the stylet guide comprises a preformed curve sized to be disposed within the subintimal space;

penetrating the inner layer of the wall of the artery from the subintimal space with a distal end of the stylet into the lumen of the artery beyond the occlusion;

decoupling the access device from the stylet;

advancing a balloon catheter comprising a stent over the stylet after decoupling the access device from the stylet, wherein a portion of the stent is within the subintimal space adjacent the occlusion and a distal end of the balloon catheter is disposed within the portion of the lumen of the artery beyond the occlusion; and

expanding a balloon and the stent of the balloon catheter, wherein a bypass blood flow lumen is formed in the subintimal space adjacent the occlusion,

wherein the distal end of the stylet penetrates the wall of the artery opposite the first catheter such that the distal end of the stylet is disposed within tissue surrounding the artery.

13. The method of claim 12, further comprising:
advancing a second catheter over the stylet guide and stylet, wherein a portion of the second catheter is within the subintimal space and a distal end of the second catheter is disposed within the portion of the lumen of the artery beyond the occlusion; and
aspirating blood through the second catheter to confirm that the distal end of the second catheter and the distal end of the stylet are disposed within the portion of the lumen of the artery beyond the occlusion.

14. The method of claim 12, wherein operating the first actuator comprises releasing the spring mechanism coupled to the stylet.

15. The method of claim 12, wherein the stylet comprises a sharp distal end.

16. The method of claim 12, wherein the first catheter comprises a distal end comprising a ramped surface.

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17. The method of claim 12, wherein a second actuator comprises a sliding button coupled to the stylet guide, wherein displacement of the sliding button displaces the stylet guide.

18. The method of claim 17, wherein the preformed curve is aligned with the sliding button.

19. A method of accessing a lumen of an artery at a second access site, comprising:

percutaneously accessing a first portion of the lumen of the artery at a first access site; advancing a guidewire into the lumen of the artery and into a subintimal space of a wall of the artery;

advancing a catheter over the guidewire into the subintimal space;

advancing a guide tube from the catheter toward a second portion of the lumen of the artery such that a distal end of the guide tube is substantially orthogonal to an inner layer of the wall of the artery;

displacing a stylet relative to the guide tube,

wherein the distal end of the guide tube remains in the subintimal space when the stylet is displaced into the second portion of the lumen of the artery, and

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wherein a distal portion of the guide tube comprises a preformed curve sized to be disposed within the subintimal space; and

penetrating the inner layer of the wall of the artery from the subintimal space with a distal end of the stylet into the lumen of the artery through a second access site in the inner layer of the wall of the artery,

wherein the distal end of the stylet penetrates the wall of the artery opposite the catheter such that the distal end of the stylet is disposed within tissue surrounding the artery.

20. The method of claim 19, wherein a first actuator advances the guide tube.

21. The method of claim 20, wherein a second actuator displaces the stylet.

22. The method of claim 19, wherein the lumen of the artery comprises an occlusion and the occlusion is disposed between the first access site and the second access site.

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